



**U.S. Department of Justice**

*United States Attorney  
Southern District of New York*

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86 Chambers Street, 3rd floor  
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January 5, 2021

**BY ECF**

The Honorable Mary Kay Vyskocil  
United States District Judge  
Daniel Patrick Moynihan United States Courthouse  
500 Pearl Street  
New York, New York 10007

Re: *Pfizer Inc. v. United States Department of Health and Human Services, et al.*, No. 20 Civ. 4920 (MKV)

Dear Judge Vyskocil:

This Office represents the defendants (the “Government”) in the above-referenced action. We write respectfully in light of the supplemental letter brief filed by Plaintiff Pfizer Inc. on December 30, 2020 (ECF No. 58), discussing an HHS-OIG regulation regarding Anti-Kickback Statute (“AKS”) safe harbors (85 Fed. Reg. 77684 (Dec. 2, 2020)), and a recently issued district court opinion discussing the AKS (*United States v. Regeneron Pharma, Inc.*, No. 20 Civ. 11217, 2020 WL 7130004 (D. Mass. Dec. 4, 2020)). *See* ECF No. 58.

First, Defendants note that Pfizer’s submission should arguably be stricken entirely, given that Pfizer did not observe the Court’s individual practice directing that “[s]ur-reply memoranda will not be accepted without prior permission of the Court.” Moreover, as reflected in Pfizer’s letter (ECF No. 58 at 3), the relevant HHS-OIG regulation and district court opinion were both issued before Pfizer filed its Reply and Opposition Memorandum (ECF No. 53), and therefore could have been discussed therein; Pfizer’s choice not to do so does not warrant a second bite at the apple.

If the Court elects to accept Pfizer’s supplemental submission, Defendants respectfully request the Court’s leave to file a short letter briefly responding to certain characterizations in Pfizer’s letter. Thank you for your consideration of this matter.

Respectfully submitted,

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